

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: 49931-0080

Applicant(s): Edward W. MERRILL *et al.*

Confirmation No.: 6478

App. No.: 10/696,709

Group Art Unit: 1796

Filing Date: October 30, 2003

Examiner: S. Berman

Title: RADIATION AND MELT TREATED ULTRA HIGH MOLECULAR
WEIGHT POLYETHYLENE PROSTHETIC DEVICES

REQUEST FOR REFUND

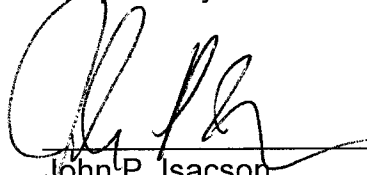
United States Patent and Trademark Office
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

Applicants filed a Request for Continued Examination, Amendment and Request for Reconsideration Under 37 CFR § 1.114, Information Disclosure Statement, and Petition for Extension of Time on July 27, 2007 (copy attached). Applicants inadvertently authorized payment of 4 independent claims in the amount of \$800.00.

Applicants respectfully request that a refund in the amount of \$800.00 be credited to Deposit Account No. 50-3840 since Applicants do not need to pay for excess claims previously paid for prior to the filing of the Request for Continued Examination.

Respectfully submitted,



John P. Isacson
Reg. No. 33,715

June 12, 2008
Date

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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL **(Submitted Only via EFS-Web)**

Application Number	10/696,709	Filing Date	2003-10-30	Docket Number (if applicable)	49931-0080	Art Unit	1711
First Named Inventor	Edward W. MERRILL et al.			Examiner Name	S. Berman		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
 Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

☐ Other _____

☒ Enclosed

☒ Amendment/Reply

☒ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☒ Other

Petition for Extension of Time/Declaration Under 37 CFR 1.131

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
 (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

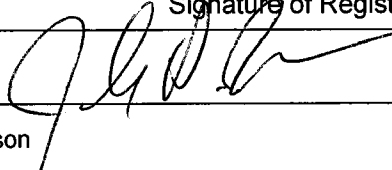
The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to
 Deposit Account No 503840

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

Signature of Registered U.S. Patent Practitioner			
Signature		Date (YYYY-MM-DD)	2007-07-27
Name	John P. Isacson	Registration Number	33715

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)**FY 2005***(fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818))*

Docket Number

49931-0080

In re Application of	Edward W. MERRILL et al.		
Application Number	10/696,709	Filed	October 30, 2003
For	RADIATION AND MELT TREATED ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE PROSTHETIC DEVICES		
Art Unit	1711	Examiner	S. Berman

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter appropriate fee below):

	Large Entity Fee	Small Entity Fee	
<input type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$ 120	\$ 60	\$ _____
<input type="checkbox"/> Two months (37 CFR 1.17(a)(2))	\$ 450	\$ 225	\$ _____
<input type="checkbox"/> Three months (37 CFR 1.17(a)(3))	\$ 1020	\$ 510	\$ _____
<input type="checkbox"/> Four months (37 CFR 1.17(a)(4))	\$ 1590	\$ 795	\$ _____
<input checked="" type="checkbox"/> Five months (37 CFR 1.17(a)(5))	\$ 2160	\$ 1080	\$ 2160.00

- ☐ Applicant claims small entity status. See 37 CFR 1.27.
- ☐ A check in the amount of the fee is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached. **WARNING: Information on this form may become public. Credit card information should not be included on this form.**
- ☐ The Director has already been authorized to charge fees in this application to a Deposit Account.
- ☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number **50-3840**.

I have enclosed a duplicate copy of this sheet.

- I am the ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).
- ☒ attorney or agent of record. Registration Number **33,715**
- ☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

July 27, 2007

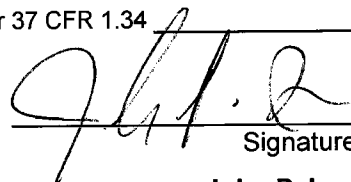
Date

(202) 416-6800

Telephone Number

61263

Customer No.



Signature

John P. Isacson

Typed or printed name

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No: 49931-0080

Applicant(s) Edward W. MERRILL et al.

Confirmation No.: 6478

App. No.: 10/696,709

Group Art Unit: 1711

Filing Date: October 30, 2003

Examiner: S. Berman

Title: RADIATION AND MELT TREATED ULTRA HIGH MOLECULAR
WEIGHT POLYETHYLENE PROSTHETIC DEVICES

AMENDMENT AND RESPONSE FOR RECONSIDERATION
UNDER 37 CFR § 1.114

Commissioner for Patents
United States Patent and Trademark Office
Randolph Building **MAIL STOP RCE**
401 Dulany Street
Alexandria, VA 22314

Sir:

Applicants herein respond to the Office Action mailed September 28, 2006 (Paper No. 20060903). Applicants filed a Notice of Appeal on December 27, 2006. Applicants respectfully request entry of the following amendments to the application and request reconsideration of the rejections of record in view of the following remarks.

Applicants petition for a five-month extension of time, as well as any other needed extension, and provide the requisite fee herewith. Please debit any underpayments, or credit any overpayments, to firm deposit account no. 50-3840.

AMENDMENTS TO THE CLAIMS

Please amend claims as set forth below:

1-123. (Cancelled).

124. **(Currently amended)** A method for fabricating an orthopedic implant prosthesis bearing, comprising the steps of:

pre-annealing a polyethylene preform at a temperature greater than ambient temperature and less than the decomposition temperature of the polyethylene for a period of time greater than 30 minutes;

irradiating the polyethylene preform, thereby ~~[[to]]~~ crosslinking the polyethylene preform; and

quenching residual free radicals in the polyethylene preform.

125. (Previously presented) The method of claim 124, further comprising the steps of:

cooling the preform after the quenching step to a temperature below the melting temperature of the polyethylene; and

forming the preform into a prosthetic bearing.

126. **(Currently amended)** A method for fabricating an orthopaedic implant prosthesis bearing comprising the steps of:

pre-annealing an ultrahigh molecular weight polyethylene preform;

irradiating the ultrahigh molecular weight polyethylene preform, thereby ~~[[to]]~~ crosslinking the ultrahigh molecular weight polyethylene preform;

quenching residual free radicals in the ultrahigh molecular weight polyethylene preform subsequent to the irradiating step; and

forming the ultrahigh molecular weight polyethylene preform into a prosthetic bearing.

127. **(Currently amended)** A method for fabricating an orthopaedic implant prosthesis bearing comprising the steps of:

pre-annealing a polyethylene preform;

irradiating the polyethylene preform, thereby ~~[[to]]~~ crosslinking the polyethylene preform;

quenching residual free radicals in the polyethylene preform subsequent to the irradiating step; and

forming the polyethylene preform into a prosthetic bearing.

128. (Withdrawn) A method for fabricating an orthopedic implant prosthesis bearing, comprising the steps of:

melting a polyethylene preform for a period of time greater than about 30 minutes;

irradiating the polyethylene preform to crosslink the polyethylene preform; and
quenching residual free radicals in the polyethylene preform.

129. (Withdrawn) The method of claim 128, further comprising the steps of:

cooling the preform after the quenching step to a temperature below the melting temperature of the polyethylene; and

forming the preform into a prosthetic bearing.

130. (Withdrawn) A method for fabricating an orthopaedic implant prosthesis bearing comprising the steps of:

melting an ultrahigh molecular weight polyethylene preform;

irradiating the ultrahigh molecular weight polyethylene preform to crosslink the ultrahigh molecular weight polyethylene preform;

quenching residual free radicals in the ultrahigh molecular weight polyethylene preform subsequent to the irradiating step; and
forming the ultrahigh molecular weight polyethylene preform into a prosthetic bearing.

131. (Withdrawn) A method for fabricating an orthopaedic implant prosthesis bearing comprising the steps of:
melting a polyethylene preform;
irradiating the polyethylene preform to crosslink the polyethylene preform;
quenching residual free radicals in the polyethylene preform after an irradiation;
and
forming the polyethylene preform into a prosthetic bearing.

132. (Withdrawn) The method according to claim 128, wherein the polyethylene is ultrahigh molecular weight polyethylene.

133. (Withdrawn) A method for fabricating an orthopaedic implant prosthesis bearing comprising the steps of:
irradiating a polyethylene preform that has been melted, thereby crosslinking the polyethylene
quenching residual free radicals in the polyethylene preform after an irradiation;
and
forming the polyethylene preform into a prosthetic bearing.

134. (Withdrawn) The method according to claim 133, wherein the polyethylene is ultrahigh molecular weight polyethylene.

REMARKS

Claims 124-134 are pending in the application. Claim 128-134 are withdrawn by the examiner. Claims 124, 126 and 127 are amended for clarity, as described below. Therefore, no new matter is introduced. The office action is discussed below.

Election/Restriction:

On page 2 of the Office Action, the examiner has withdrawn claims 128-134 allegedly as being directed to a non-elected invention. The examiner asserts that the terms "melting" and "pre-annealing" are not synonymous. The examiner believes that the term "pre-annealing" encompasses thermal treatment at various temperatures other than the melting temperature or temperatures above melting and refers that the dictionary definition of "annealing" is heating a material and cooling it slowly. Applicants respectfully disagree with the examiner indicate that the term "pre-annealing" encompasses thermal treatment at various temperatures including the melting temperature or temperatures above melting. Therefore, the "melting" step is synonymous with the "pre-annealing" step in a process of fabricating a polymeric material. Applicants reiterate for the record that "pre-annealing" is used as a synonym for "melting" in the US Patent 6,562,540 (Saum *et al.*, the '540 patent). See Saum *et al.* for example, col. 4, lines 23-25, col. 6, lines 35-38, that describes pre-annealing of UHMWPE at a temperature greater than about 280°C (which is well above the melting point of the UHMWPE).

Therefore, withdrawal of the restriction and rejoinder of the claims 128-134 are solicited.

Withdrawal of Indefiniteness Rejection:

On page 2 of the Office Action, the examiner has indicated withdrawal of the indefiniteness rejection of claim 124. The claim has been amended accordingly to address the issue raised by the examiner. However, on page 6 of the Office Action, the examiner recited the rejection. Applicants request withdrawal of the rejection or an explanation in this regard.

Response to Arguments:

Written Description Rejection:

On pages 4-5 of the Office Action, the examiner has maintained the alleged rejection of claims 124-127 for various written description-related reasons.

On pages 3-4 of the Office Action, with respect to the rejections under 35 USC 112, first paragraph, applicants refer that it is well-known that 175°C is less than the decomposition temperature of UHMWPE (see for example, Saum, *et al.* US 6,562,540, col. 6, lines 34-41, discloses UHMWPE is pre-annealed to a temperature of 280°C to 355°C, preferably 320°C to 355°C, without reaching its decomposition temperature. That is, the decomposition temperature of the UHMWPE is much higher than 175°C.

Applicants also point out to the specification for the support for 175°C and other temperatures. For example, specification at page 30 describes temperatures of “about 145°C to about 230°C, and more preferably, is about 175° to about 200°C.” The specification also describes that “the heating is maintained so to keep the polymer at the preferred temperature for about 5 minutes to about 3 hours, and more preferably for about 30 minutes to about 2 hours.”

With respect to the recitation “greater than 30 minutes”, the examiner complains that there is no recognition in the specification as filed that greater than 30 minutes is a significant time period. Applicants refer to above that the specification, for example, at page 30 describes “the preferred temperature [is] about 5 minutes to about 3 hours, and more preferably [is] about 30 minutes to about 2 hours.” Applicants also refer to specification, for example, at Example 3, at page 41, that the temperature varied “between 200°C at the base to 175°C at the top.... [and] was held at these temperatures for a period of 30 minutes before starting the irradiation.” The heating was continued until “[a]fter irradiation, the heating was stopped and the cup was allowed to cool to room temperature.” The specification, thus clearly discloses “pre-annealing” for a period of time “greater than 30 minutes”, because the heating continued until after irradiation and then cool slowly (which satisfies examiner’s asserted definition of “annealing” or “pre-annealing”, see above and page 2 of the Office Action). Therefore, the specification has full support for the claim recitation of

"pre-annealing a polyethylene preform at a temperature greater than ambient temperature and less than the decomposition temperature of the polyethylene for a period of time greater than 30 minutes."

Applicants also reiterate regarding the range limitation, that the duration of "30 minutes" is within the range of "about 5 minutes to about 3 hours" as described above. Therefore, the range limitation for a period of time "greater than 30 minutes" is fully supported by the specification (See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), MPEP 2163.05 III at 2100-189 to 190 (Rev. 3, August 2005)).

Withdrawal of the rejection is therefore solicited.

Anticipation/Obviousness Rejections:

On pages 6-7 of the Office Action, the examiner has maintained the alleged anticipation and obviousness rejections of claims 124-127 in view of Salovey (the '264 patent), Shalaby (the '411 patent) and/or Sun (the '049 patent) of the record.

With respect to the rejection of claims over Salovey *et al.*, on page 3 of the Office Action, the examiner asserted that the declarations filed in the related cases (see US Serial No. 10/197,263, filed July 18, 2002, declarations filed pursuant to 37 C.F.R. § 1.131 evidencing completion of the claimed invention prior to January 20, 1995, and the Salovey '264 patent is not a prior art) are not of record in the instant application. In response, applicants herewith submit a copy of the declaration to antedate Salovey. Applicants also submit that the instant claims are entitled to section 120 priority date of 02-13-1996 or 10-13-1996, since the original specification has support for "pre-annealing at a temperature greater than ambient temperature and less than the decomposition temperature of the polyethylene for a period of time greater than 30 minutes", as discussed above.

On pages 3-4 of the Office Action, with respect to the instant claim recitation of "irradiating the polyethylene preform to crosslink the polyethylene preform", the examiner states that Shalaby, Salovey, or Sun's "low dose irradiation" or "sterilization irradiation" is encompassed by the instantly claimed phrase "irradiating the polyethylene preform". Applicants disagree with the examiner and point out that the "low dose

irradiation" or "sterilization irradiation" of Shalaby, Salovey, or Sun would generate residual free radicals and would not be "quenching residual free radicals in the ultrahigh molecular weight polyethylene preform subsequent to the irradiating step", as required by the claimed method. Therefore, Salovey, Shalaby, and/or Sun does not disclose the claimed method.

On page 4 of the Office Action, the examiner also complains that the claim phrase "to crosslink the polyethylene preform" is a statement of intended purpose and not a patentable weight. The examiner believes that the irradiation, as disclosed by Shalaby or Sun, would be expected to crosslink the polyethylene. Applicants refer to above discussion and submit that the "low dose irradiation" or "sterilization irradiation" of Salovey, Shalaby, or Sun would generate residual free radicals and would not be "quenching residual free radicals in the ultrahigh molecular weight polyethylene preform subsequent to the irradiating step", as required by the claimed method. Therefore, Salovey, Shalaby, and/or Sun does not anticipate the claimed methods nor make the claimed methods obvious.

In addition, applicants indicate that the claim phrase "to crosslink the polyethylene preform" is also recited in the claims of the '540 Saum patent (see claim 1, at col. 16, lines 60-61, for example). Without acquiescing in the rejection, in order to expedite the prosecution and for clarity, Applicants amend claims 124, 126, and 127 to recite "irradiating the ultrahigh molecular weight polyethylene preform, thereby crosslinking the ultrahigh molecular weight polyethylene preform."

Therefore, withdrawal of the anticipation/obviousness rejection is requested.

Double Patenting Rejection:

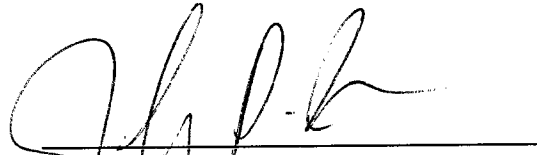
On pages 4 and 8-10 of the Office Action, the examiner also has maintained the provisional rejection of claims 124-127 under the judicially created doctrine of obviousness-type double patenting allegedly as being unpatentable over pending claims of co-pending applications serial nos. 10/948,440, 10/197,209, 10/696,362, 10/901,089 and 10/197,263.

Applicants reiterate that none of the cited co-pending applications have received a notice of allowance, therefore, the merits of this provisional rejection need not be discussed at this time. See MPEP § 822.01.

REQUEST

Applicants submit that claims 124-127 are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,



John P. Isacson
Reg. No. 33,715

July 27, 2007
Date

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: 49931-0080

Applicant(s) Edward W. MERRILL et al.

Confirmation No.: 6478

App. No.: 10/696,709

Examiner: S. Berman

Filing Date: August 30, 2003

Group Art Unit: 1711

Title: RADIATION AND MELT TREATED ULTRA HIGH MOLECULAR WEIGHT
POLYETHYLENE PROSTHETIC DEVICES

**INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56 and 37 CFR §1.97**

United States Patent and Trademark Office
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

Submitted herewith on Form PTO/SB/08A is a listing of documents known to applicants in order to comply with applicants' duty of disclosure pursuant to 37 C.F.R. §1.56 and §1.97. A copy of each of the listed documents are being submitted to comply with the provisions of 37 C.F.R. §1.97-1.99.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or is considered to be material to patentability as defined in 37 C.F.R. §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* prior art reference against the claims of the present application.

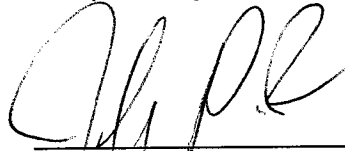
Applicants believe that the instant Information Disclosure Statement is being filed after the mailing of a first Office action on the merits but before the mailing date of either (1) a final action under §1.113; (2) a notice of allowance under §1.311; or (3) an

action that otherwise closes prosecution in the application. The Commissioner is hereby authorized to charge the required fee in the amount of \$180.00 in accordance with 37 CFR §1.17(p) to Deposit Account No. 50-3840.

English translations of the foreign-language documents may not be readily available; however, the absence of such translations does not relieve the PTO from its duty to consider the submitted documents (37 CFR §1.98 and MPEP §609).

Applicants respectfully request that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08A be returned in accordance with M.P.E.P. §609.

Respectfully submitted,



John P. Isacson
Reg. No. 33,715

July 27, 2007

Date

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Phone: (202) 416-6800
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Customer No. 61263

Sheet 1 of 1 Form PTO/SB/08A				ATTY DOCKET NO. 49931-0080		APPLICATION NO. 10/696,709	
LIST OF REFERENCES CITED BY APPLICANT(S)				APPLICANT(S) Edward W. MERRILL et al.			
Date Submitted: July 27, 2007				FILING DATE October 30, 2003		GROUP 1711	
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL	DOCUMENT NUMBER	DATE (M/D/Y)	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	C01	5,874,123	Park	427	2.24		
	C02	4,281,420	Raab	3	1.912		
	C03	5,019,105	Wiley	623	22		
FOREIGN PATENT DOCUMENTS							
	DOCUMENT NUMBER	DATE (M/D/Y)	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO	
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)							
	C04	RÖMPP CHEMIE LEXIKON 3760-3766 (German)					
	C05	RÖMPP CHEMIE LEXIKON 3760-3766 (English translation)					
	C06	Encyclopedia of Material Technology 776-785 (German)					
	C07	Encyclopedia of Material Technology 776-785 (English translation)					
	C08	Bhateja et al.	Polymer Journal 21(9): 739-750 (1989)				
	C09	Bhateja et al.	J. Macromol. Sci. – Phys. B29(1): 1-10 (1990)				
	C10	Bhateja et al.	J.M.S. – Rev. Macromol. Chem. Phys. C35(4): 581-659 (1995)				
	C11	Hsieh et al.	Journal of Applied Polymer Science 53(3): 347-354 (2003) (Abstract)				
	C12	Jones et al.	Wear 70: 77-92 (1981)				
	C13	Kanig	Colloid & Polymer Sci. 260: 356-377 (1982) (German)				
	C14	Kanig	Colloid & Polymer Sci. 260: 356-377 (1982) (English translation)				
	C15	Lue	Effects of Gamma Irradiation and Post Heat-Treatments on the Structure and Mechanical Properties of Ultra High Molecular Weight Polyethylene (UHMW-PE)				
	C16	Sakai et al.	Polymer 34(16): 3362-3367 (1993)				
	C17	Sun et al.	Polymer Engineering and Science 29(21): 1503-1510 (2004) (Abstract)				
	C18	Wang et al.	Journal of Applied Polymer Science 34: 593-599 (1987)				
	C19	Witkiewicz et al.	Journal of Biomedical Materials Research 33(2): 73-82 (1998) (Abstract)				
EXAMINER				DATE CONSIDERED			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.